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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,354	02/06/2002	Joseph A. Kozlowski	AL01381K	4273

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
COPPINS, JANET L	

ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,354	KOZLOWSKI ET AL.	
	Examiner	Art Unit	
	Janet L. Coppins	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *61-126* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *61-126* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on June 8, 2005 has been entered.

2. Accordingly, claims 1-160 have been cancelled and new claims 61-26 are now pending in the instant application.

Election/Restrictions

3. The Markush group set forth in the claims includes both independent and distinct inventions, and patentably distinct compounds (or species) within each invention. However, this application discloses and claims a plurality of patentably distinct inventions far too numerous to list individually. Moreover, each of these inventions contains a plurality of patentably distinct compounds, also far too numerous to list individually. For these reasons provided below, restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 61-85, 90, and 112-126, drawn to compounds and compositions, classified in various subclasses of classes 544, 546, 548, or 564. A further election of a single disclosed species will be required if this Group is elected.

II. Claims 86 and 89, drawn to methods of stimulating cannabinoid CB2 receptors, using compounds according to claim 61, classified in various subclasses of class

514. A further election of a single disclosed species will be required if this Group is elected, in addition to a single disclosed condition or disease to be treated.

III. Claims 87-88, drawn to various methods of treating, using compounds according to claim 61, classified in various subclasses of class 514. A further election of a single disclosed species will be required if this Group is elected, in addition to a single disclosed condition or disease to be treated.

IV. Claim 91, drawn to a process of making a pharmaceutical composition, classified in various subclasses of classes 544, 546, 548, or 564. A further election of a single disclosed species will be required if this Group is elected, in addition to an election of a single disclosed process of preparation.

V. Claims 92-95, drawn to methods of treating rheumatoid arthritis, using compounds according to claims 61 and 67, classified in various subclasses of class 514. A further election of a single disclosed species will be required if this Group is elected.

VI. Claims 96-99, drawn to a composition for treating rheumatoid arthritis that contains a compound according to claims 61 and 67 and additional ingredients, classified in various subclasses of class 514. A further election of a single disclosed species will be required if this Group is elected, in addition to specific additional compounds or ingredients.

VII. Claims 100-101, drawn to methods of treating multiple sclerosis, using compounds according to claims 61 and 67, classified in various subclasses of

class 514. A further election of a single disclosed species will be required if this Group is elected.

VIII. Claims 102-103, drawn to a composition for treating multiple sclerosis that contains a compound according to claims 61 and 67 and additional ingredients, classified in various subclasses of class 514. A further election of a single disclosed species will be required if this Group is elected, in addition to specific additional compounds or ingredients.

IX. Claims 104-107, drawn to methods of treating psoriasis, using compounds according to claims 61 and 67, classified in various subclasses of class 514. A further election of a single disclosed species will be required if this Group is elected.

X. Claims 108-111, drawn to a composition for treating psoriasis that contains a compound according to claims 61 or 67 and additional ingredients, classified in various subclasses of class 514. A further election of a single disclosed species will be required if this Group is elected, in addition to specific additional compounds or ingredients.

In addition to an election of one of the above Groups, restriction is further required under 35 U.S.C. 121 as follows:

4. In accordance with the decisions in ***In re Harnisch***, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and ***Ex parte Hozumi***, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984), restriction of a Markush group is proper where the compounds within the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to

that utility. In addition, a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the other members obvious under 35 U.S.C. 103.

5 Where an election of any one of Groups I-X is made, an election of a single disclosed compound (in the specification) is further required, including an exact definition of each substituent on the base molecule, wherein a **single member** at each substituent group or moiety is selected. For example, the base molecules has the substituent R^1 group wherein R^1 is recited to contain many variables, including hydrogen, alkyl, haloalkyl, cycloalkyl, distinct heteroaryl ring systems, so that applicant must select a single defined moiety for R^I. In the instant case, the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar thereto as to be within the same inventive concept and reduction to practice). The scope of an independent invention will encompass all compounds within the scope fop the claim which fall into the same class and subclass as the elected compound (or set of compounds). Examination will then proceed on the elected compound AND the entire scope of the invention encompassing the elected species, as defined by the above Groups and common classification. Should applicant traverse on the ground that the compounds are not patentable distinct, applicant should submit evidence now of record showing the compounds to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other.

All compounds falling outside the class(es) and subclass(es) of the selected compound and other compounds encompassed by the elected Group above will be directed to nonelected subject matter and will be withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R. 1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject matter. (The provisions of 35 U.S.C. 121 apply with regard to double patenting covering divisional applications).

6. Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventors must be amended in compliance with 37 CFR 1.48(b) if one of the currently named inventors is no loner an inventor of at least one claims remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 DFR 1.48)b) and by the fell required under 37 DFR 1.17)I).

7. Markush claims must be provided with support in the disclosure for each member of the Markush group. See MPEP 608.01(p). Applicant should exercise caution in making a selection of a single member for each substituent group on the base molecule to be consistent with the written description.

Rationale Establishing Patentable Distinctiveness Within Each Group

8. Each Group listed above is directed to or involves the use of compounds and compositions which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects and reactive conditions (MPEP 806.04, MPEP 808.01). Additionally, the level of skill in the art is not such that one invention would be obvious over either of the other inventions (Groups), i.e. they are patentable over each other. Chemical structures that are similar are presumed to

function similarly, whereas chemical that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrefutable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holdings of **Applications of Papesch**, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and **In re Lalu**, 223 USPQ 1257 (Fed. Cir, 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

The above Groups represent general areas wherein the inventions are independent and distinct, each from the other because of the following reasons:

9. Invention I is related to each of Inventions II, III, V, VII, and IX as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product since the instantly claimed compounds are recited as useful for treating many different and varied diseases, for example, rheumatoid arthritis, glaucoma, shock, asthma, and melanoma. Therefore separate search conditions are involved, which would impose a burden if unrestricted.

10. The Inventions of Group I are related as mutually exclusive species in the Markush group of the formula of claim 61. The species are distinct and independent from each other because the compounds differ structurally, one from the other as defined by the different variables recited in

the claims. For example, within claim 1, the variable R^1 alone has many separate, generic possibilities, including, for example, distinct heterocyclic ring systems, which cannot be said to belong to the same class and subclass of chemical classification. Absent factual evidence to the contrary, each is a different chemical compound.

11. Inventions I and IV are related as process of making and product made. These inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different products or (2) that the product can be made by another materially different process (MPEP 806.05(f)). In the instant case, the product as claimed can be made by another materially different process as demonstrated by the the schemes and examples in the specification.

12. Inventions II, III, V, VII, and IX are distinct and independent from Invention IV because they are directed to different statutory classes of invention and the practice of one of the Inventions would not result in the practice of the other, i.e. treating multiple sclerosis is not a process that prepares *per se* the compounds.

13. Each of the different methods of use set forth in Invention Sets II, III, V, VII, and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of se together and they have different modes of operation, different functions, or different effects (MPEP 806.04, MPEP 808.01). Methods of use are unrelated if one of three differences can be found between them. These differences are 1) the population being treated, 2) the material being used, and 3) the methodology for treatment. If any one or more of those differences exist and are patentably distinct, then the methods are unrelated. In the instant case, the different methods of use inventions are unrelated because the patient population treated for each method is divergent.

For example, a method of treating diabetes presumes that the patients being treated are diabetic, while a method of treating MS presumes the patients are suffering from multiple sclerosis.

14. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-III, restriction for examination purposes as indicated is proper.

Advisory of a Rejoinder

15. The following is a recitation of MPEP 821.04, Rejoinder:

> Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02(c) and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.
> Where the application as originally filed discloses the product and the process for making and/or using the product, and only claims directed to the product are presented for examination, when a product claim is found allowable, applicant may present claims directed to the process of making and/or using the patentable product by way of amendment pursuant to 37 CFR 1.121. In view of the rejoinder procedure, and in order to expedite prosecution, applicants are encouraged to present such process claims, preferably as dependent claims, in the application at an early stage of prosecution. Process claims which depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance. Amendments submitted after final rejection are governed by 37 CFR 1.116. Process claims which do not depend from or otherwise include the limitations of the patentable product will be withdrawn from consideration, via an election by original presentation (see MPEP § 821.03). Amendments submitted after allowance are governed by 37 CFR 1.312. Process claims which depend from or otherwise include all the limitations of an allowed product claim and which meet the requirements of 35 U.S.C. 101, 102, 103, and 112 may be entered.
>
> Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either: (A) elect the invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and examined under 37 CFR 1.129(b)(2); or (B) elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found patentable, process claims which either depend from or include all the limitations of the allowable product will be rejoined. If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37 CFR 1.129(b)(2) even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26(a) states that "[T]he Commissioner may refund any fee paid by mistake or in excess of that required. A change of purpose after the payment of a fee...will not entitle a party to a refund of such fee..." In this case, the fees paid under 37 CFR 1.129(b) were not paid by mistake nor paid in excess, therefore, applicant would not be entitled to a refund. In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the

> rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

136. The following is a recitation from paragraph five, "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. 103(b)" (1184 TMOG 86(March 26, 1996)):

> "However, in the case of an elected product claim, rejoinder will be permitted when a product claim is found allowable and the withdrawn process claim **depends from or otherwise includes all of the limitations of** an allowed product claim. Withdrawn process claims not commensurate in scope with an allowed product claim will not be rejoined." (emphasis added)

Therefore, in accordance with MPEP 821.04 and In re Ochiai, 71 F. 3d 1565, 37 USPQ 1127 (Fed. Cir. 1995), rejoinder of product claims with process claims commensurate in scope with the allowed product will occur following a finding that the product claims are allowable. Until, such time, a restriction between product claims and process claims is deemed proper. Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution to maintain either dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

17. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Coppins whose telephone number is 571.272.0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 571.273.8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Coppins
March 16, 2006

Joseph K. McKane
SPE, Art Unit 1626